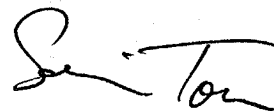


DECLARATION

I, Sabine Frieda Katharina Town, declare that I am a citizen of the Federal Republic of Germany, residing at Waldstraße 45, 82386 Oberhausen, Federal Republic of Germany, that I am fluent in German and English, that I am a competent translator from German into English and that the attached is a true and accurate translation made by me into the English language of International Patent Application No. PCT/EP98/06961 dated 03.11.1998.

I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.

I hereby subscribe my name to the foregoing declaration, this fifteenth day of March 2000.



Sabine F.K. Town

Translation

PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

5620

(PCT Article 36 and Rule 70)

09/530747

Applicant's or agent's file reference 4817/0B/WO-Kn	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP98/06961	International filing date (day/month/year) 03 November 1998 (03.11.98)	Priority date (day/month/year) 04 November 1997 (04.11.97)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68		
Applicant ROCHE DIAGNOSTICS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 09 March 1999 (09.03.99)	Date of completion of this report 09 February 2000 (09.02.2000)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP98/06961

## I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

- ☐ the international application as originally filed.
- ☒ the description, pages 1 - 36, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims, Nos. \_\_\_\_\_, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. 1 - 9, filed with the letter of 17 November 1999 (17.11.1999),  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the drawings, sheets/fig 1/7 - 7/7, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

3. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

See Supplemental Box

**I. Basis of the report**

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

The amendments submitted by letter of 17 November 1999 introduce subject matter going beyond the scope of the application as filed and hence contravening PCT Article 34(2)(b). This applies to the following amendments:

Claim 1: the amplicates that are formed are not larger than 75 nucleotides;

Claim 4: the amplicates that are formed are not larger than 61 nucleotides.

For that reason, the assessment under Box V, below, is based on the original set of claims.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

### 2. Citations and explanations

The following documents are referred to:

- D1: EP-A-0 229 701 (CETUS CORP.) 22 July 1987;
- D2: US-A-5 527 898 (BAUER HEIDI M. ET AL.) 18 June 1996;
- D3: US-A-5 538 848 (LIVAK KENNETH J. ET AL.) 23 July 1996;
- D4: WO-A-95/02690 (ABBOTT LAB.) 26 January 1995.

D3 discloses a method for detecting nucleic acids, from which the subject matter of Claim 1 differs in that the length of the amplicates formed with the help of primers is less than 100 nucleotides.

D1 discloses the detection of viruses, whereby a 91bp fragment is amplified and detected with the help of a probe. The subject matter of Claims 1, 2, 4, 5 and 9 is not considered novel in the light of D1 and D3.

D2 discloses the use of probes covering the entire sequence located between the primers used for amplification. It also describes non-specific probes and primers. Consequently, the subject matter of Claims 3 and

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

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6-8 can not be considered inventive in relation to D1 and D2.

Very short amplicates commonly arise in the amplification of viral nucleic acids. The present application even refers, on page 12, line 22, to nucleic acids with viral origins, which, as a rule, only yield very short transcription products, because of their structure. In D4, amplicates of less than 60bp are described. The subject matter of Claim 4 is therefore not considered inventive in the light of D1 and D4.

Consequently, the subject matter of Claims 1-9 does not satisfy the requirements of PCT Article 33(3).

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Contrary to the requirements of PCT Rule 5.1(a)(ii), neither the relevant prior art disclosed in D1-D4, nor those documents themselves, are mentioned in the description.